K120391

510(k) Summary
for
MR 4500

DEC 2 1 2012

1. SPONSOR

Warday Premise Limited
Hampton Court Estate
Summer Road
Thames Ditton
Surrey, KT7 0SP, UK

Telephone: +44(0)20 8398 9911

Date Prepared: February 1, 2012

2. Device Name

Proprietary Name:	MR 4500
Common/Usual Name:	Wheelchair
Classification Name:	Wheelchair, Mechanical
Classification Number:	890.3850
Product Code:	IOR

3. PREDICATE DEVICES

Invacare Corp, Tracer Series, K935398, March 1, 1994

Classification Name:	Wheelchair, Mechanical
Classification Number:	890.3850
Product Code:	IOR

4. INTENDED USE

The MR4500 is an adult Manual Mechanical Wheelchair intended to provide mobility to person limited to the sitting position as a transport chair within a healthcare facility.

5. DEVICE DESCRIPTION

The Wardray Premise MR 4500 is a manually operated wheelchair that is propelled by human power. Its intended function and use is to provide mobility to person limited to a sitting position. It may be used as an attendant propelled

transport device in a healthcare environment such as a hospital, nursing home or extended care facility. The wheelchair consists primarily of an aluminum frame; 12inch rear wheels and 5-inch front casters and handles for the wheelchair to be pushed. It is folding or non-rigid type of wheelchair that is designed for use by a patient weighing up to 280 lbs.

The frame is constructed of one inch (1) outside diameter Aluminum tube that is welded that has a wall thickness of 1/8 inch. The rear urethane wheels are fixed and front are urethane casters.

6. TECHNOLOGICAL CHARACTERISTICS

The MR4500 is constructed from the following materials: Aluminum alloys, 6063 T6 and 6082 T4, Stainless Steel EN 100883/1.44044 and Brass CW614 N which allows the chair to be used safely in a MRI environment up to and including 7 Tesla.

7. SUBSTANTIAL EQUIVALENCE

The Wardray Premise MR 4500 is substantially equivalent to Invacare Corporation Tracer series manual wheelchairs (ALB19HBFR). The above device was granted marketing clearance by the FDA on March 1st 1994, under 510K number K935398. When the MR4500 is compared to the predicate device their is no difference in safety and effectiveness.

8. PERFORMANCE STANDARDS

No performance standards applicable to this device have been adopted under Section 514 of the Act. The MR 4500 manual wheelchair is designed to meet the applicable requirements of ISO 7176 – Standard for manual Wheelchairs for this intended use.
The MR4500 passed a 24 hour sustained 100% overload test, a determination of Strength.
The MR4500 has been tested and data provided for 7.0, 3.0 and 1.5 T MR systems environments. The magnetic field strength and magnetic field spatial gradient data showed that no magnetically induced displacement force was produced in the MR4500 up to and including 7.0T MR system. The MR4500 meets the ASTM F2503-8 requirements to be labeled MR Conditional up to and including 7.0T.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Wardray Premise, Limited
% Maelor Group, Incorporated
James Wason Ph.D.
7 Village Woods Drive
Amherst, New Hampshire 03031

December 21, 2012

Re: K120391
Trade/Device Name: MR4500 Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: IOR
Dated: December 03, 2012
Received: December 10, 2012

Dear Dr. Wason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K120391

Device Name: MR4500 Wheelchair

Indications For Use:

The MR4500 is an adult Manual Mechanical Wheelchair intended to provide mobility to person limited to the sitting position as a transport chair within a healthcare facility.

Prescription Use _____ (Part 21 CFR 801 subpart D)

OR

Over-The-Counter Use __X___ (Part 21 CFR 801 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian D. Pullin -S

Division of Neurological and
Physical Medicine Devices
510(k) Number: K120391